

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: November 9, 2022

OLIVIA TILLEY,

*

No. 14-818V

*

Petitioner,

*

Special Master Sanders

v.

*

*

SECRETARY OF HEALTH
AND HUMAN SERVICES,

*

Dismissal; Insufficient Proof; Human

*

Papillomavirus (“HPV” or “Gardasil”)

*

Vaccine; Premature Ovarian Failure/

Respondent.

*

Primary Ovarian Insufficiency (“POF/POI”)

*

Mark T. Sadaka, Law Offices of Sadaka Associates, LLC, Englewood, NJ, for Petitioner.

Debra A. Filteau Begley, U.S. Department of Justice, Washington, DC, for Respondent.

DISMISSAL DECISION¹

On September 5, 2014, Lisa Tilley (“Mrs. Tilley”) filed a petition for compensation on behalf of her then-minor daughter, Olivia Tilley (“Petitioner”) under the National Vaccine Injury Compensation Program² (“Vaccine Program” or “Program”). 42 U.S.C. § 300aa-10 to 34 (2012). Pet. at 1, ECF No. 1. The petition alleges that the human papillomavirus (“HPV” or “Gardasil”) vaccinations Petitioner received on June 26, 2009, August 26, 2009, and August 10, 2011, caused her to suffer from premature ovarian failure (“POF”). *Id.* The information in the record, however, does not show entitlement to an award under the Program.

On September 28, 2016, Respondent filed his Rule 4(c) report. Resp’t’s Report, ECF No. 27. Respondent argued that Petitioner had not satisfied her burden of proof under *Althen*, as “[s]her [sic] has not offered a medical theory causally connecting the HPV vaccines to her injury, none of her treating doctors attributed her condition to her HPV vaccines, and [she] has not established that the onset of her condition was temporally appropriate.” *Id.* at 5. Following the submission of

¹ This Decision shall be posted on the United States Court of Federal Claims’ website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, the I agree that the identified material fits within the requirements of that provision, such material will be deleted from public access.

² National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755 (“the Vaccine Act” or “Act”). Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

several rounds of expert reports, this case was consolidated with several other POI matters to determine if any of the cases could proceed in light of the causation theory proposed in each of the petitioners' cases. *See, e.g.*, ECF Nos. 41–52, 55–65, 67–68, 70, 72–84. On December 6, 2019, I held a status conference with the parties to discuss the presentation of the parties' arguments with respect to the viability of a causation theory pursuant to *Althen* prong one. *See* Min. Entry, docketed Dec. 6, 2019; *see also* No. 15-183V, ECF No. 80. Petitioner filed her brief on *Althen* prong one on June 18, 2020. No. 15-183V, ECF No. 86. Respondent submitted a response on September 22, 2020, and Petitioner filed a reply on November 20, 2020. No. 15-183V, ECF Nos. 88, 90.

I issued a ruling on *Althen* prong one on August 30, 2021, finding that the petitioners in the consolidated POI cases have presented a causation theory that, while not applicable to all of them, does survive *Althen* prong one under limited, specific circumstances. *See* Findings of Fact at 24, ECF No. 87. On December 14, 2021, I held a status conference in this matter to discuss whether preponderant evidence has been submitted showing that Petitioner suffers from POI with an autoimmune etiology so that she may proceed under *Althen* prongs two and three. Sched. Order at 1, ECF No. 89. Petitioner requested sixty days to file updated medical records, including antibody test results, and a status report indicating whether this case will proceed or be dismissed, and I granted her request. *See id.* Petitioner filed an unopposed motion for an extension of time to file the requested information on February 14, 2022. ECF No. 90. I stayed Petitioner's motion and ordered her to file a status report indicating whether the case will proceed with expert reports; and/or an explicit motion to supplement Petitioner's request for more time to file medical records containing additional objective testing. ECF No. 91. On March 15, 2022, Petitioner filed a supplemental motion for an extension of time alleging that she plans to undergo further antibody testing but needed to be off of certain medications prior to testing and providing a timeline for the submission of such evidence. ECF No. 92.

I held a status conference with the parties on April 12, 2022. Min. Entry, docketed Apr. 12, 2022. During the conference, the parties discussed the relevancy of additional antibody testing, along with the additional factors set forth in my ruling on *Althen* prong one that will aid in my determination of vaccine-causation. *See* ECF No. 93. Petitioner again requested sixty days to file a status report or other filing identifying evidence regarding her basis to proceed with *Althen* prongs two and three consistent with the factors outlined in my ruling on *Althen* prong one. I denied Petitioner's motion as moot and ordered her to file updated medical records containing antibody testing, if applicable, and a status report indicating that the case will not proceed or outlining the evidence she is relying on to continue with her claim. *See id.* I specifically told Petitioner to address the factors enumerated in my ruling on *Althen* prong one, aside from any recent positive antibody results if there have been years between such results and the onset of Petitioner's symptoms, and/or prior negative results. *Id.*

Following one unopposed extension of time, Petitioner filed a status report indicating that she was still in the process of arranging for additional antibody testing and requested thirty days to decide on next steps with her case. ECF No. 95. I cautioned Petitioner that without more than antibody test results from 2022, Petitioner will likely be unsuccessful in establishing the applicability of the proposed biological mechanism. ECF No. 96. I denied Petitioner's request for

additional time and ordered her to file an expert report on *Althen* prongs two and three within sixty days. *See id.*

On August 4, 2022, I held a status conference with the parties to discuss the ongoing critical deficiencies in the record concerning evidence of an autoimmune etiology in this case. *See* ECF Nos. 97–99; *see also* Min. Entry, docketed Aug. 4, 2022. Respondent agreed with my concerns. ECF No. 99. I terminated Petitioner’s deadline to file an expert report and ordered her to file a status report indicating how she wished to proceed or an appropriate motion within thirty days. *See id.* Petitioner then filed a motion for a thirty-day extension of time, which I denied, and ordered her to file an appropriate motion by September 21, 2022. ECF Nos. 100–01. Specifically, I indicated that “[a]fter a careful review of the record,” Petitioner has not presented preponderant evidence that satisfies her claim pursuant to *Althen* prongs two and three. *See* ECF No. 101. I noted that given the amount of time that has elapsed since the filing of the petition, and the fact that Petitioner’s complete medical record has been filed, additional time would “not overcome the current state of the record.” *See id.* I ordered Petitioner to file an appropriate motion within two weeks. *Id.* I warned the parties that if Petitioner did not meet this deadline, Respondent could file a motion for a ruling on the record by September 28, 2022. *Id.*

On Petitioner’s deadline, she filed a status report requesting an additional week to decide how she wished to proceed. ECF No. 102. I accordingly ordered Respondent to file a motion for a ruling on the record. ECF No. 103. Respondent missed his deadline and filed an unopposed motion for an extension of time to file his motion for a ruling on the record, which I granted. ECF No. 104; Non-PDF Order, docketed Oct. 6, 2022. On October 21, 2022, Respondent filed a motion to dismiss Petitioner’s claim. ECF No. 105. I ordered Petitioner to file her response by November 4, 2022. Non-PDF Order, docketed Oct. 24, 2022. Instead of filing a response, Petitioner filed an unopposed motion to voluntarily dismiss her claim on November 1, 2022. ECF No. 106. Petitioner requested a decision dismissing her claim and ending all rights in the Vaccine Program. *Id.* at 1.

To receive compensation under the Program, Petitioner must prove either (1) that she suffered a “Table Injury”—i.e., an injury falling within the Vaccine Injury Table—corresponding to the vaccination, or (2) that she suffered an injury that was actually caused by a vaccine. *See* §§ 13(a)(1)(A), 11(c)(1). An examination of the record did not uncover persuasive evidence that Petitioner suffered from a “Table Injury.” Further, the record does not contain persuasive evidence that Petitioner’s injuries were caused-in-fact by her HPV vaccinations, as she cannot show by a preponderant standard that her POI is autoimmune in nature. *See, e.g.,* ECF No. 101.

Under the Act, petitioners may not be given a Program award based solely on their claims alone. Rather, the petition must be supported by medical records or the opinion of a competent physician. § 13(a)(1). In this case, the medical record is insufficient to prove Petitioner’s claim, and at this time, Petitioner has not filed sufficient supporting evidence. Therefore, this case must be **dismissed for insufficient proof. The Clerk shall enter judgment accordingly.**³

IT IS SO ORDERED.

³ Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties’ joint filing of a notice renouncing the right to seek review.

s/Herbrina D. Sanders
Herbrina D. Sanders
Special Master